SUMMARY OF SAFETY AND EFFECTIVE USE

510(k) Number: K111892

JUL 28 2011

Date Prepared: 31 May 2011

Submitter Information

Submitter: Vital Images, Inc. Street Address: 5850 Opus Parkway Suite 300 Minnetonka, MN 55343-4414 Establishment registration: 2134213 Owner/Operator #: 9024582	Contact Person: Ian Nemerov Vice President, General Counsel & Secretary Phone: (952) 487-9622 Fax: (952) 487-9510 Email: inemerov@vitalimages.com

Device Information

Trade Name	VitreaView
Common Name	Radiological Image Processing Software
Classification Name	System, Image Processing, Radiological
Regulation /Product Code	21 CFR 892.2050
Product Code	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

VitreaView is substantially equivalent to the previously-cleared, web-based software Cedara WebAccess™

Predicate Device

Predicate Device	**Manufacturer**	**FDA 510(k)**
Cedara WebAccess™	Cedara Software Corp. Mississauga, Ontario, Canada	K092915

Device Description

VitreaView is a cross-browser, cross-platform zero-footprint universal image viewer solution capable of displaying both DICOM and non-DICOM medical images. VitreaView enables referring clinicians and other medical professionals with access to patients' medical images in a seamless way, with integrations into their Electronic Health Record (EHR), Electronic Medical Record (EMR), and Health Information Exchange (HIE)

VitreaView offers medical professionals a universal viewer for accessing imaging data in context with reports from enterprise patient health information databases, fosters collaboration, and provides workflows and interfaces appropriate for referring physicians and clinicians. IT departments will not have to incur time to install client systems, due to the zero-footprint, zero-

download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases.

Some of the general features include:

- 2D multi-modality review of data
- Basic 2D review tools (zoom, pan, measure)
- Easy study navigation
- Comparative review
- Displays of DICOM and non-DICOM images
- A scalable, virtualizable infrastructure
- Cross-platform viewing capabilities (Windows, Mac OS, etc.)
- Leveraging of next-generation protocols for image viewing (i.e. MINT)
- Single sign-on
- EMR integration

Intended Use/Indications for Use

VitreaView is a medical image viewing and information distribution application that provides access, through the Internet and within the enterprise, to multi-modality softcopy medical images, reports and other patient-related information, that may be hosted within disparate archives and repositories for review, communication and reporting of DICOM and non-DICOM data. VitreaView is not intended for primary diagnosis.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Summary of Testing

The software was designed, developed and tested according to written procedures. Software testing was completed to insure the new feature function according to the requirements and interacts without impact to existing functionality. The test results support a determination of substantial equivalence.

Conclusions

VitreaView has similar indications for use as the predicate device and essentially identical technological characteristics. Minor feature differences do not raise any new questions regarding safety or effectiveness of the device. The VitreaView software performs as intended, and presents no unacceptable risks to the intended patient population or end user. VitreaView is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Vital Images, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 28 2011

Re: K111892
Trade/Device Name: VitreaView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture arching and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 1, 2011
Received: July 5, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) number (if known) K111892

Device Name: VitreaView

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Prescription Use ___X__	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Devices
Evaluation and Safety
510(k) K111892
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